REMARKS

The Examiner makes final his restriction requirement. Applicants do not cancel the withdrawn claims (claims 12 to 20) herein as each of those claims depends ultimately from claim 1 and, upon allowance of claim 1, which is necessarily generic to those claims, Applicants will be entitled to have those claims considered pursuant to 37 CFR § 1.141(a).

Before addressing the merits of the Office Action, Applicants note that the Examiner indicated in the Office Action Summary that initialed PTO-1449s from Applicants' Information Disclosure Statements were attached to the Office Action, however, none were provided. Applicants request that the Examiner attach the copies of the initialed PTO-1449s to the next Office Action on the merit.

The Invention

Surgery has become common for replacing or repairing the anterior cruciate ligament (ACL) in a human knee. In such surgery, bone tunnels are appropriately aligned and formed in both the proximal tibia and the distal femur and graft material is somehow rigidly coupled, usually with bone blocks to be inserted into these tunnels, to fix the material in a proper position for long term use in the body in place of the original ligament.

It is well known that intimate contact between the graft material and the walls of the bone tunnels aids in ensuring an effective, efficient healing process, however, another potential problem may arise even where the graft material appears to be successfully fixed within the bone tunnel. Bone tunnels are usually drilled for a considerable length into the femur for fixation of the graft material in ACL replacement procedures. Where exactly within the tunnel the graft is fixed often depends on the manner of fixation and tensioning of the graft material, but often the site for fixation is chosen as the place where the fixation device best allows fixing. Where the fixation takes place inside the bone tunnel apart from the bone tunnel edge at the distal end of the femur, the graft material that extends from the fixation point to the edge of the bone tunnel often moves or slides within this remaining portion of the tunnel. This phenomenon is known to some surgeons as the "windshield wiper" effect. As noted above, movement tends to prevent healing and fixation of the soft tissue to bone, so where the windshield wiper effect occurs, the

portion of the graft that moves when the patient uses the reconstructed joint may never heal completely in the region near the edge of the bone tunnel. This potential problem defeats the goal of most surgeons which is to have the graft material fix as close as possible to its natural fixation point before being damaged by injury or disease. This natural fixation point is generally at the edge of the bone tunnel, where the graft will not fix if the windshield wiper effect is present.

The present invention provides a ligament graft fixation system for fixing ligament graft material within a bone tunnel in a way that better approximates the natural fixation point of the ligamentary material that is being replaced. The system of the invention includes an expandable fixation member having a ***graft receiving eyelet disposed proximate its distal end***, opposed bone engaging elements disposed about its periphery, and an ***expansion plug receiving opening defined in its proximal end***. The system also includes an expansion plug having a diameter greater than the diameter of the expansion plug receiving opening so that forceable insertion of the expansion plug into the expansion plug receiving opening causes an expansion of the expandable fixation member to drive the opposed bone engaging elements apart so as to fix the bone engaging elements, as well as the graft material, in a bone tunnel. These elements are recited in each independent claim in the application (i.e., claims 1 and 21).

FIG. 1 (provided below) provides an illustration of one such system of the invention having a fixation member 20, an expansion plug 21 positioned at a proximal end 110 of the fixation member, and a graft material holding element in the form of an eyelet 24 located proximate to a distal end 112 (or leading end – the end that is inserted into the bone tunnel) of the fixation member. Graft material 200 can be passed through eyelet 24 so that two ends 201 of the graft trail fixation member 20 proximally. An insertion element 114 mates with fixation member 20 and expansion plug 21 and extends proximally. In use, a surgeon inserts fixation member 20 along with graft material 200 into a prepared bone tunnel using insertion element 114 until the graft and fixation member are in the desired position for graft fixation within the tunnel. Insertion element 114 can then be actuated or manipulated by the surgeon to force expansion plug 21 distally into fixation member 20 to cause the fixation member to expand and thereby fix the graft material to the interior of the bone tunnel.

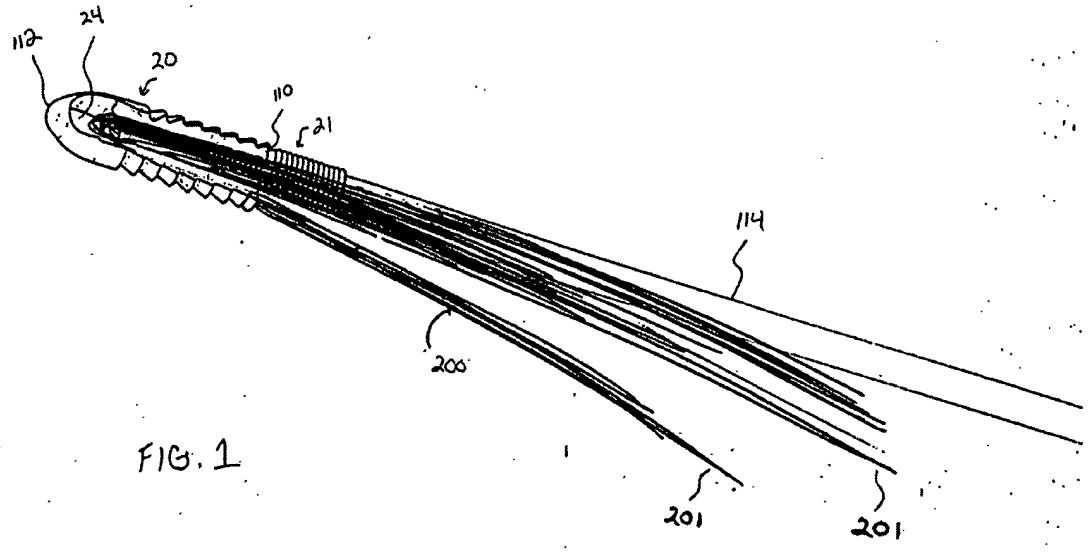


FIG. 1

As can be partially seen in FIG. 1, but which is more clearly illustrated in FIGS. 2, 2A and 2B of the application (which illustrate a side view, a proximal end view, and a lengthwise cross-section, respectively, of fixation member 20) and as is recited in claim 5, fixation member 20 includes ***cut out passages or grooves 23 extending proximally along the fixation member from each of the two opposed sides of eyelet 24.***

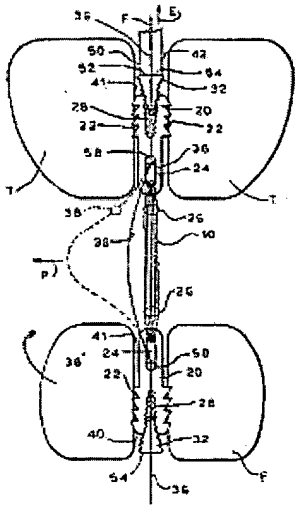
The fixation system of the invention having a distal graft holding element and a proximal bone plug receiving opening (and optionally grooves extending proximally from the graft holding element) allows for fixation at the proximal end of the fixation member, which can be placed proximate to the edge of the bone tunnel to fix the graft as close to the anatomically correct position as desired.

The Office Action

The Examiner rejects claims 1-11 and 21 (all claims considered) under 35 USC § 102(b) as being anticipated by Li (U.S. patent no. 5,707,395). In particular, the Examiner states that, "Li discloses ligament bone anchor (20) having expansion plug (34) and graft eyelet as is claimed (abstract, figures 1-17 and column 6 lines 14-67)."

Li provides the exact opposite configuration when compared to the present claims. That is, where claims 1 and 21 recite a distal graft holding eyelet, Li provides a proximal eyelet.

Where claims 1 and 21 recite a proximal plug receiving opening, Li provides a distal plug receiving opening. This can best be illustrated by reference to Figure 2 of Li which is provided on Li's front page:



Because Li's eyelet is proximal, the anchor body 20 does not press the ligament graft against the wall of the bone tunnel in the way that Applicants' claimed system does because in claims 1 and 21, the graft holding eyelet is on the distal or leading end of the system and the graft material must pass proximally over the expandable fixation element and its proximal expansion plug receiving opening in order to extend out of the mouth of the bone tunnel. Again, Li's configuration is the opposite of that illustrated in Figure 1 of the present application and recited in present claims 1 and 21.

This difference with Li is further clarified in independent method claim 21 in which the orientation of the fixation element is further expressly recited with respect to the bone tunnel and in dependent claim 5, which provides proximally extending grooves to seat ligament graft portions as they pass over the expandable fixation member – Li has no such grooves because its device is oriented so that the graft material does not pass over the anchor body.[1]

[1] Claim 5 is amended herein to change its directional reference from "distally" to "proximally." The "distally" reference was an error and the correct orientation (and support for the amendment) can be found in the application at least at page 5, lines 27-30, and in the figures.

Conclusion

In view of the above, each of the presently pending claims in this application is believed to be in immediate condition for allowance. Accordingly, the Examiner is respectfully requested to pass this application to issue.

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Respectfully submitted,

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